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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,530	02/21/2002	Sanjeev Redkar	12636-267	8656

21971 7590 01/19/2005

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,530

Applicant(s)

REDKAR ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/22/08
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response and Terminal Disclaimer dated 12/22/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The claim is a dependent claim that reference to itself. The examiner is confused as to show to apply the independent limitations to a claim that reference to itself. Clarification and amendment of this claim is required.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-8, 10-20 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the disclosures of Wall et al (USPN 6,288,072 hereafter '072). The claims are drawn to a polymorph of a 9-nitrocamptothecin and a pharmaceutical formulation comprising such.

2. The '072 reference discloses camptothecin formulation (abstract), including 9-nitrocamptothecin compounds (col. 5, lin. 45-50, col. 6, lin. 15-20). The camptothecin

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compounds include solvates, hydrates and polymorphs (col. 4, lin. 25-30). The compounds are placed into pharmaceutical formulations comprising carriers (col. 8, lin. 35-col. 11, lin. 29). The reference however is silent to the particular properties of the claims.

3. The reference is silent to the differential scanning calorimetry readings as well as the X-ray powder diffraction, or the Kappa radiation characteristics. However, since applicant has not disclosed a specific 9-nitrocamptothecin compound, nor defined the specific activity of the compound it is the position of the examiner that such limitation do not impart patentability on the instant compound and would be inherent to any 9-nitrocamptothecin compound. Applicant is invited to provide evidence of a patentable distinction between the functions of the instant compound and that of the prior art, since the compound must be defined by its function and not by its properties. Also applicant must provide a specific structure of the instant compound. As a compound camptothecin has multiple positions for additions and functional groups. Applicant has only provided one functional group, which does not clearly define the structure of the instant claims. Therefore, applicant is requested to provide the specific structure and function of the camptothecin compound of the instant claims.

Further regarding claim 5, it is the position of the examiner that such a limitation does not impart patentability on the claim. The limitation that the polymorph is obtained by grinding renders the claim a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the

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claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature” than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

4. With these things in mind, regarding the inherency of the 9-nitrocamptothecin of ‘072, the disclosures of the reference render the claims anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-8, and 14-20 rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the disclosures of Wall et al (USPN 6,288,072 hereafter '072). The claims are drawn to a 9-nitrocamptothecin compound and a pharmaceutical formulation comprising such.

8. Referencing the 102 discussions, the '072 patent discloses a 9-nitocamptothecin compound in a pharmaceutical formulation. The reference however is silent to the specific properties recited by applicant. Applicant however is reminded that the prior art need not disclose each and every limitation of the prior art in order to obviate the invention. Burden is placed upon applicant to provide patentable distinctions between the instant invention and that of the prior art. Applicant claims a 9-nitocamptothecin compound placed in a pharmaceutical formulation. The '072 reference teaches this invention. Applicant has not provided a distinction in the functionality of the instant invention, and barring a showing of these distinctions in addition to a showing of criticality to the recited limitations, the claims will remain obviated by the '072 disclosures.

9. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993),

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Ex parte Gray, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

10. With these things in mind one of ordinary skill in the art would be motivated to follow the teachings and suggestions of '072 in order to apply a pharmaceutical formulation comprising a polymorph of a 9-nitrocamptothecin to a cancer regimen. It would have been obvious to follow these disclosures and teachings with an expected result of an anti-tumor formulation comprising a camptothecin compound.

11. Claims 9 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Wall et al (USPN 6,288,072 hereafter '072) and Comins et al (USPN 5,162,532 hereafter '532). The claims are drawn to a 9-nitrocamptothecin compound and a pharmaceutical composition comprising such. The camptothecin is crystallized with tetrahydrofuran.

12. As discussed above the '072 patent discloses a 9-nitrocamptothecin compound. The reference is however is silent tot specific solvent used to process the compound, however their use is well known and well within the level of ordinary skill in the art. As seen in the '532 patent that discloses camptothecin analogues such as 9-nitro (col. 6, lin. 64-68) processed using solvents such as tetrahydrofuran and acetonitrile (col. 3, lin. 45-50). A skilled artisan would be motivated to process the compounds of '072 with the solvents of '532 in order to properly process the camptothecin compounds allowing for improved pharmaceutical properties.

13. With these things in mind one of ordinary skill in the art would have been motivated to process the camptothecin analogue of '072 with the solvent of '532 in order to ensure proper

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processing of the compound. It would have been obvious to, and well with the level of skill in the art to combine these disclosures with an expected result of a cancer-fighting compound with improved delivery properties.

Response to Arguments


14. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

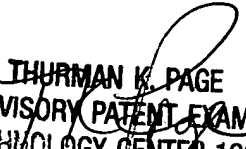
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615


MP Young


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